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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,411	12/12/2003	Matthew F. Brown	PC25082A	1172

28523 7590 10/26/2005

PFIZER INC.
PATENT DEPARTMENT, MS8260-1611
EASTERN POINT ROAD
GROTON, CT 06340

EXAMINER	
OWENS, AMELIA A	
ART UNIT	**PAPER NUMBER**
1625	

DATE MAILED: 10/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/734,411	BROWN ET AL.	
	Examiner	Art Unit	
	Amelia A. Owens	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-10* is/are allowed.

6)☒ Claim(s) *11-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-15 are pending.

Double Patenting

2. The rejection under the judicially created doctrine of obviousness-type double patenting as being unpatentable over US applications 10/198237, 10/346684, 10759562, 10/759555 has been dropped. The applications are not commonly owned so there is no double patenting issue.

The applications are not applicable as prior art as the claimed compounds have a C(O)CH2XY(R4)(R5)P(O)R6R7 group not present in any of applications 10/198237, 10/346684, 10759562, 10/759555. Motivation is lacking to replace the Z1(Y)X1 group of 10/198237, 10/346684, 10759562, 10/759555 with the instant C(O)CH2XY(R4)(R5)P(O)R6R7 group.

Claim Rejections - 35 USC § 112

3. The rejection of claims 11-15 under 35 USC 112, 2nd paragraph, is dropped in view of applicants comments.

4. The rejection of claims 1-10 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement has been dropped. The compounds have the ability to inhibit chemotaxis and therefore may have utility as a general anti-inflammatory. See disclosure @ page 29 lines 20-28.

5. Claims 11-15 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The state of the art is that CCR1 receptors are known to bind several CC chemokines. Saeki et al, CCR1 Chemokine Receptor Antagonist, Current Pharmaceutical Design, 2003, 9, 1201-1208, @ 1201 column 2, paragraph 2 teach CCR1 receptor binds chemokines MIP-1alpha and RANTES. Saeki also teaches that CCR1 *may* be a therapeutic target for a variety of diseases. (see abstract). Saeki further teaches that blockade of CCR1 may have therapeutic potential in rheumatoid arthritis (RA). See page 1203 @ column 1 paragraph 1. The art indicates the *potential* of chemokines binding to CCR1, but clinical trials are needed to determine if the targets have promise.

Applicants remarks have been fully considered but are not found persuasive. It is noted that binding OR not binding is not a utility. It is not seen where inhibiting MIP-1alpha and/or RANTES binding is associated with the myriad of diseases/conditions claimed by applicant. Cook, SCIENCE 269, 15 September 1995, 1583-1585, @ 1583 column 1 lines 1-9, teach MIP-1alpha and RANTES are members of the same chemokine family.

The disclosure of the present invention is a method of treating and preventing diseases mediated by inhibiting MIP-1alpha and/or RANTES wherein the claimed compound is administered to a subject. Hence, the amount of guidance presented in the specification the absence of data indicating that a particular disease/condition (especially those of claim 12) do not occur when the claimed compound is administered, and the state of the prior art indicating that treatment *of some diseases via binding of MIP-1alpha and/or RANTES (in particular RA- see Saeki above)* is possible, all indicate that treatment, not prevention of diseases/conditions is possible. See - Can We Prevent Parkinson's and Alzheimer's disease? column 1 @ lines 1-7 that teach no preventive or long term effective strategies are available for Alzheimer's which is one of the named conditions in claim 12. Further, the generally accepted approach to treating HIV involves antiretrovirals and not antiinflammatories. It is generally accepted that HIV cannot be prevented. Therefore, the amount of guidance necessary to perform applicant's invention would result in undue experimentation because the skilled artisan would be forced to randomly test numerous diseases to determine which ones, of any, could be prevented by administering the claimed compound.

Contra to applicants remarks, the specification does not disclose publications directed to treating conditions mediated by inhibiting the production of metalloproteinases and cytokines at inflammatory sites. The abstract of Li et al, Interplay of matrix metalloproteinases, tissue inhibitors of metalloproteinases and their regulators in cardiac matrix remodeling, Cardiovascular Research 46 (2000) 214-224, suggests a relationship between myocardial fibrosis and modulating metalloproteinase activity. The art does not teach a nexus between metalloproteinases and the conditions named by applicant in claim 15; nor does the art teach a specific benefit to inhibiting production of metalloproteinases, only a potential benefit. Applicant is invited to submit evidence that inhibition of metalloproteinases and cytokines at inflammatory sites provides a benefit. Inhibition of metalloproteinases and cytokines at

inflammatory sites per se is not viable utility. What effect is applicants' achieving by said inhibition?

6. Claims 11-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant method of treating a disease responsive to inhibiting MIP-1alpha and/or RANTES encompasses as yet unidentified diseases/conditions responsive to the activity, a description of which is not found in the specification.

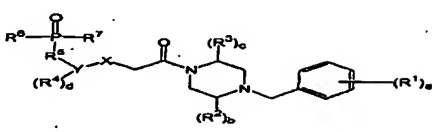
The instant method of treating a disease responsive to inhibiting production of metalloproteinases and cytokines at inflammatory sites encompasses as yet unidentified diseases/conditions responsive to the activity, a description of which is not found in the specification.

Duplicate Claims

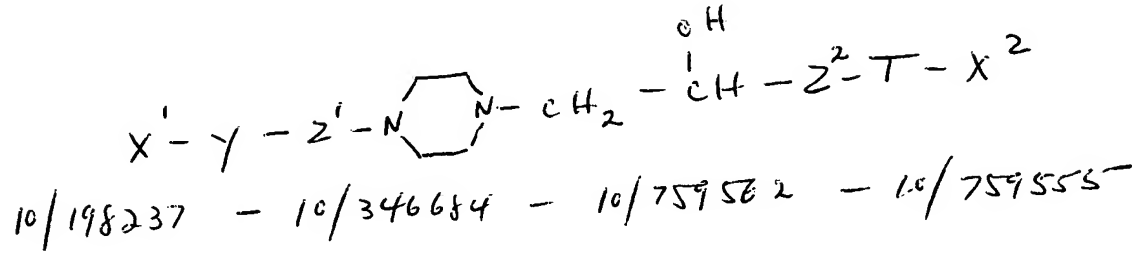
7. Claims 11 is objected to under 37 CFR 1 .75 as being a substantial duplicate of claim 12. The recitation of the use in claim 12 (treat condition mediated by..) does not further limit the method of claim 11. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP
7O6.03(k).

Allowable Subject Matter

8. Saeki et al teaches CCR1 binds MIP-1alpha and/or RANTES thereby treating RA. Saeki further teach structures of reported CR1 antagonists in figure (1). Note formula 10 is a piperazine structurally similar to the claimed piperazine. The difference is the instant piperazine has –(R5)P(O)R6R7 group not present in the prior art compound. See below. Thus, the prior art neither teaches nor suggests the claimed compounds. Claims 1-10 are allowed.



← Applicant



Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amelia A. Owens whose telephone number is 571-272-0690. The examiner can normally be reached on Monday - Friday..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amelia A. Owens
Primary Examiner
Art Unit 1625